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Transgenic animals of the invention have uses which include, but are not limited to, animal model systems useful in elaborating the biological function of polypeptides of the present invention, studying conditions and/or disorders associated with aberrant expression, and in screening for compounds effective in ameliorating such conditions and/or disorders.

Example 14: Knock-Out Animals

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Endogenous gene expression can also be reduced by inactivating or "knocking out" the gene and/or its promoter using targeted homologous recombination. (E. g., see Smithies et al., Nature 317: 230-234 (1985); Thomas & Capecchi, Cell 51: 503512 (1987); Thompson et al., Cell 5: 313-321 (1989); each of which is incorporated by reference herein in its entirety). For example, a mutant, non-functional polynucleotide of the invention (or a completely unrelated DNA sequence) flanked by DNA homologous to the endogenous polynucleotide sequence (either the coding regions or regulatory regions of the gene) can be used, with or without a selectable marker and/or a negative selectable marker, to transfect cells that express polypeptides of the invention in vivo. In another embodiment, techniques known in the art are used to generate knockouts in cells that contain, but do not express the gene of interest. Insertion of the DNA construct, via targeted homologous recombination, results in inactivation of the targeted gene. Such approaches are particularly suited in research and agricultural fields where modifications to embryonic stem cells can be used to generate animal offspring with an inactive targeted gene (e. g., see Thomas & Capecchi 1987 and Thompson 1989, supra). However this approach can be routinely adapted for use in humans provided the recombinant DNA constructs are directly administered or targeted to the required site in vivo using appropriate viral vectors that will be apparent to those of skill in the art.

In further embodiments of the invention, cells that are genetically engineered to express the polypeptides of the invention, or alternatively, that are genetically engineered not to express the polypeptides of the invention (e. g., knockouts) are administered to a patient *in vivo*. Such cells may be obtained from the patient (I. e., animal, including human) or an MHC compatible donor and can include, but are not limited to fibroblasts, bone marrow cells, blood cells (e. g., lymphocytes), adipocytes, muscle cells, endothelial cells etc. The cells are genetically engineered *in vitro* using recombinant DNA techniques to introduce the coding sequence of polypeptides of the invention into the cells, or

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alternatively, to disrupt the coding sequence and/or endogenous regulatory sequence associated with the polypeptides of the invention, e. g., by transduction (using viral vectors, and preferably vectors that integrate the transgene into the cell genome) or transfection procedures, including, but not limited to, the use of plasmids, cosmids, YACs, naked DNA, electroporation, liposomes, etc.

The coding sequence of the polypeptides of the invention can be placed under the control of a strong constitutive or inducible promoter or promoter/enhancer to achieve expression, and preferably secretion, of the polypeptides of the invention. The engineered cells which express and preferably secrete the polypeptides of the invention can be introduced into the patient systemically, e. g., in the circulation, or intraperitoneally.

Alternatively, the cells can be incorporated into a matrix and implanted in the body, e. g., genetically engineered fibroblasts can be implanted as part of a skin graft; genetically engineered endothelial cells can be implanted as part of a lymphatic or vascular graft. (See, for example, Anderson et al. U. S. Patent 5,399,349; and Mulligan & Wilson, U. S. Patent 5,460,959 each of which is incorporated by reference herein in its entirety).

When the cells to be administered are non-autologous or non-MHC compatible cells, they can be administered using well known techniques which prevent the development of a host immune response against the introduced cells. For example, the cells may be introduced in an encapsulated form which, while allowing for an exchange of components with the immediate extracellular environment, does not allow the introduced cells to be recognized by the host immune system.

Transgenic and "knock-out" animals of the invention have uses which include, but are not limited to, animal model systems useful in elaborating the biological function of polypeptides of the present invention, studying conditions and/or disorders associated with aberrant expression, and in screening for compounds effective in ameliorating such conditions and/or disorders.

All patents, patent publications, and other published references mentioned herein are hereby incorporated by reference in their entireties as if each had been individually and specifically incorporated by reference herein. While preferred illustrative embodiments of the present invention are described, one skilled in the art will appreciate that the present invention can be practiced by other than the described embodiments.

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which are presented for purposes of illustration only and not by way of limitation. The present invention is limited only by the claims that follow.

CLAIMS

We claim:

- 1. An isolated nucleic acid molecule comprising
- (a) a nucleic acid molecule comprising a nucleic acid sequence that encodes
 an amino acid sequence of SEQ ID NO: 111 through 201;
 - (b) a nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 1 through 110;
 - (c) a nucleic acid molecule that selectively hybridizes to the nucleic acid molecule of (a) or (b); or
- 10 (d) a nucleic acid molecule having at least 60% sequence identity to the nucleic acid molecule of (a) or (b).
 - 2. The nucleic acid molecule according to claim 1, wherein the nucleic acid molecule is a cDNA.
 - 3. The nucleic acid molecule according to claim 1, wherein the nucleic acid molecule is genomic DNA.
- 4. The nucleic acid molecule according to claim 1, wherein the nucleic acid molecule is a mammalian nucleic acid molecule.
 - 5. The nucleic acid molecule according to claim 4, wherein the nucleic acid molecule is a human nucleic acid molecule.
- 6. A method for determining the presence of a prostate specific nucleic acid (PSNA) in a sample, comprising the steps of:
 - (a) contacting the sample with the nucleic acid molecule according to claim 1 under conditions in which the nucleic acid molecule will selectively hybridize to a prostate specific nucleic acid; and
- 30 (b) detecting hybridization of the nucleic acid molecule to a PSNA in the sample, wherein the detection of the hybridization indicates the presence of a PSNA in the sample.

- 7. A vector comprising the nucleic acid molecule of claim 1.
- 8. A host cell comprising the vector according to claim 7.

9. A method for producing a polypeptide encoded by the nucleic acid molecule according to claim 1, comprising the steps of (a) providing a host cell comprising the nucleic acid molecule operably linked to one or more expression control sequences, and (b) incubating the host cell under conditions in which the polypeptide is produced.

- 10. A polypeptide encoded by the nucleic acid molecule according to claim 1.
- 11. An isolated polypeptide selected from the group consisting of:
- (a) a polypeptide comprising an amino acid sequence with at least 60% sequence identity to of SEQ ID NO: 111 through 201; or
 - (b) a polypeptide comprising an amino acid sequence encoded by a nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 1 through 110.
- 12. An antibody or fragment thereof that specifically binds to the polypeptide 20 according to claim 11.
 - 13. A method for determining the presence of a prostate specific protein in a sample, comprising the steps of:
- (a) contacting the sample with the antibody according to claim 12 under
 conditions in which the antibody will selectively bind to the prostate specific protein; and
 - (b) detecting binding of the antibody to a prostate specific protein in the sample, wherein the detection of binding indicates the presence of a prostate specific protein in the sample.
- 30 14. A method for diagnosing and monitoring the presence and metastases of prostate cancer in a patient, comprising the steps of:

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- (a) determining an amount of the nucleic acid molecule of claim 1 or a polypeptide of claim 6 in a sample of a patient; and
- (b) comparing the amount of the determined nucleic acid molecule or the polypeptide in the sample of the patient to the amount of the prostate specific marker in
 a normal control; wherein a difference in the amount of the nucleic acid molecule or the polypeptide in the sample compared to the amount of the nucleic acid molecule or the polypeptide in the normal control is associated with the presence of prostate cancer.
- 15. A kit for detecting a risk of cancer or presence of cancer in a patient, said
 10 kit comprising a means for determining the presence the nucleic acid molecule of claim 1
 or a polypeptide of claim 6 in a sample of a patient.
- 16. A method of treating a patient with prostate cancer, comprising the step of administering a composition according to claim 12 to a patient in need thereof, wherein
 said administration induces an immune response against the prostate cancer cell expressing the nucleic acid molecule or polypeptide.
 - 17. A vaccine comprising the polypeptide or the nucleic acid encoding the polypeptide of claim 11.

SEQUENCE LISTING

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120

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